

118TH CONGRESS
2D SESSION

H. R. _____

To require the Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response, to carry out a program under which the Secretary requires each regulated seller of a highly infectious agent to comply with certain logbook requirements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. COSTA introduced the following bill; which was referred to the Committee
on _____

A BILL

To require the Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response, to carry out a program under which the Secretary requires each regulated seller of a highly infectious agent to comply with certain logbook requirements, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Preventing Illegal Lab-
5 oratories and Protecting Public Health Act of 2024”.

1 **SEC. 2. REQUIRING CERTAIN SELLERS OF HIGHLY INFEC-**
2 **TIOUS AGENTS TO KEEP A LOGBOOK OF**
3 **SALES.**

4 (a) PROGRAM.—The Secretary of Health and Human
5 Services, acting through the Assistant Secretary for Pre-
6 paredness and Response, shall carry out a program under
7 which the Secretary requires each regulated seller of a
8 highly infectious agent to comply with the logbook require-
9 ments of subsection (c).

10 (b) LIST OF HIGHLY INFECTIOUS AGENTS.—

11 (1) DEVELOPMENT.—The Secretary shall de-
12 velop and maintain a list of all agents that meet the
13 definition of a highly infectious agent in subsection
14 (f).

15 (2) INITIAL LIST.—The Secretary shall develop
16 the initial list required by paragraph (1) not later
17 than 12 months after the date of enactment of this
18 Act.

19 (3) PERIODIC REVIEW.—The Secretary shall
20 periodically review and update the list required by
21 paragraph (1).

22 (4) CONSULTATION; CONSIDERATION.—In de-
23 veloping and updating the list required by paragraph
24 (1), the Secretary shall—

25 (A) consult with relevant agencies, includ-
26 ing the Centers for Disease Control and Pre-

1 vention, the National Institutes of Health, and
2 the Department of Homeland Security;

3 (B) take into consideration the latest edi-
4 tion of “Biosafety in Microbiological and Bio-
5 medical Laboratories” published by the Centers
6 for Disease Control and Prevention and the Na-
7 tional Institutes of Health (or any successor to
8 such publication); and

9 (C) take into consideration the latest edi-
10 tion of “NIH Guidelines for Research Involving
11 Recombinant or Synthetic Nucleic Acid Mol-
12 ecules” published by the National Institutes of
13 Health (or any successor to such publication).

14 (c) LOGBOOK REQUIREMENTS.—

15 (1) IN GENERAL.—Each regulated seller shall
16 maintain, in accordance with criteria issued by the
17 Secretary, an electronic list (in this section referred
18 to as a “logbook”) of the sales by such seller of each
19 highly infectious agent on the list under subsection

20 (b) that identifies—

21 (A) the agent by name;

22 (B) the quantity sold;

23 (C) the name and address of each pur-
24 chaser, including relevant identifying business

1 information as deemed necessary by the Sec-
2 retary;

3 (D) a short description of the purchaser's
4 intended use of the agent; and

5 (E) the date and time of the sale.

6 (2) SALE REQUIREMENTS.—In the case of a
7 sale to which the requirement of paragraph (1) ap-
8 plies, the regulated seller shall not sell the highly in-
9 fectious agent unless—

10 (A) the prospective purchaser—

11 (i) presents an identification card that
12 provides a photograph and is issued by a
13 State or the Federal Government, or a
14 document that, with respect to identifica-
15 tion, is considered acceptable for purposes
16 of sections 274a.2(b)(1)(v)(A) and
17 274a.2(b)(1)(v)(B) of title 8, Code of Fed-
18 eral Regulations (or successor regulations);
19 and

20 (ii) signs the logbook and enters in
21 the logbook—

22 (I) the purchaser's name and ad-
23 dress;

1 (II) a short description of the
2 purchaser's intended use of the agent;
3 and

4 (III) the date and time of the
5 sale; and

6 (B) the regulated seller—

7 (i) determines that the name entered
8 in the logbook corresponds to the name
9 provided on such identification and that
10 the date and time entered are correct; and

11 (ii) enters in the logbook the name of
12 the highly infectious agent and the quan-
13 tity sold.

14 (3) CONTENTS.—The regulated seller shall in-
15 clude in the logbook, in accordance with criteria of
16 the Secretary, a notice to purchasers that entering
17 false statements or misrepresentations in the log-
18 book may subject the purchasers to criminal pen-
19 alties under section 1001 of title 18, United States
20 Code, which notice specifies the maximum fine and
21 term of imprisonment under such section.

22 (4) DURATION OF MAINTENANCE OF EN-
23 TRIES.—The regulated seller shall maintain each
24 entry in the logbook for not fewer than five years
25 after the date on which the entry is made.

1 (5) DISCLOSURE OF LOGBOOKS.—The Sec-
2 retary shall establish restrictions on disclosure of in-
3 formation in logbooks. Such regulations shall—

4 (A) provide for the disclosure of the infor-
5 mation as appropriate to the Secretary and to
6 Federal, State, and local law enforcement agen-
7 cies; and

8 (B) prohibit accessing, using, or sharing
9 information in the logbooks for any purpose
10 other than to ensure compliance with this sec-
11 tion or to protect public health and safety.

12 (d) FALSE STATEMENTS OR MISREPRESENTATIONS
13 BY PURCHASERS.—For purposes of section 1001 of title
14 18, United States Code, entering information in a logbook
15 shall be considered a matter within the jurisdiction of the
16 executive, legislative, or judicial branch of the Government
17 of the United States.

18 (e) **【OTHER PENALTIES OR CONSEQUENCES?】**.—
19 **【What consequences result from a violation of this section**
20 **by a regulated seller?】**

21 (f) DEFINITIONS.—In this section:

22 (1) The term “highly infectious agent” means
23 an infectious agent that meets the criteria of “risk
24 group 3” or “risk group 4” as such risk groups are
25 defined in the latest edition of “NIH Guidelines for

1 Research Involving Recombinant or Synthetic Nu-
2 cleic Acid Molecules” published by the National In-
3 stitutes of Health (or any successor to such publica-
4 tion).

5 (2) The term “regulated seller” means a seller
6 of highly infectious agents, except that such term
7 does not include an employee or agent of such a sell-
8 er.

9 (3) The term “Secretary” means the Secretary
10 of Health and Human Services, acting through the
11 Assistant Secretary for Preparedness and Response.

12 **SEC. 3. EVALUATION OF HIGH-CONTAINMENT LABORA-**
13 **TORIES.**

14 (a) IN GENERAL.—The National Security Advisor, in
15 consultation with the Secretary of Health and Human
16 Services, the Secretary of Agriculture, the Secretary of
17 Defense, the Secretary of Homeland Security, the Na-
18 tional Intelligence Council, and such other Federal offi-
19 cials as the National Security Advisor determines appro-
20 priate, shall identify a single Federal official to oversee
21 a periodic strategic evaluation of high-containment labora-
22 tories in the United States.

23 (b) TOPICS.—Each strategic evaluation under sub-
24 section (a) shall include—

25 (1) an assessment of—

1 (A) the number, location, and mission of
2 high-containment laboratories;

3 (B) the capacity of such existing labora-
4 tories to effectively meet national goals to
5 counter threats to biosafety and biosecurity;

6 (C) the aggregate risks associated with—

7 (i) such existing laboratories; and

8 (ii) expanding the numbers and facili-
9 ties of such laboratories; and

10 (D) the type of oversight needed for high-
11 containment laboratories; and

12 (2) up-to-date national standards, developed by
13 the Federal official designated under subsection (a)
14 in consultation with the scientific community, for the
15 design, construction, commissioning, operation, and
16 long-term maintenance of high-containment labora-
17 tories.

18 (c) REPORTING.—Upon completion of each strategic
19 evaluation under subsection, (a), the Federal official des-
20 ignated under subsection (a) shall submit to the President
21 and the Congress a report on the results of such evalua-
22 tion and include in each such report recommendations
23 on—

24 (1) addressing gaps in Federal oversight of
25 high-containment laboratories; and

1 (2) utilizing high-containment laboratories for
2 protecting public health and ensuring biosecurity in
3 the United States.

4 (d) PUBLIC HEALTH AND BIOSECURITY TEAM.—

5 (1) IN GENERAL.—The Federal official des-
6 ignated under subsection (a) shall maintain a team,
7 to be known as the Public Health and Biosecurity
8 Team, to serve as a single point of contact for State
9 and local agencies regarding questions of public
10 health relating to laboratory biosafety and biosecu-
11 rity.

12 (2) ESTABLISHMENT.—The Federal official
13 designated under subsection (a) shall establish the
14 Public Health and Biosecurity Team, as required by
15 paragraph (1), not later than one year after such of-
16 ficial is first designated.

17 (3) DUTIES.—The Public Health and Biosecu-
18 rity Team shall be the primary point of contact in
19 the Federal Government for State and local agencies
20 on—

21 (A) issues related to—

22 (i) oversight of high-containment lab-
23 oratories;

24 (ii) the impact of high-containment
25 laboratories on public health; or

1 (iii) connecting State and local offi-
2 cials with the relevant Federal agency or
3 agencies on matters related to high-con-
4 tainment laboratories; and

5 (B) other issues as determined necessary
6 by the Federal official designated under sub-
7 section (a).

8 (e) FEASIBILITY STUDY.—

9 (1) IN GENERAL.—The Federal official des-
10 igned under subsection (a) shall conduct a feasi-
11 bility study on establishing and maintaining a data-
12 base on existing high-containment laboratories in the
13 United States and making such database accessible
14 to State and local officials.

15 (2) DATABASE DESCRIBED.—The database to
16 be studied under paragraph (1) should be designed
17 to include, with respect to each high-containment
18 laboratory, the following information:

19 (A) The identity of the owners of the lab-
20 oratory.

21 (B) The status of any licensing or certifi-
22 cation of the laboratory required under Federal,
23 State, or local law.

24 (C) Any legal violations by, and discipli-
25 nary action taken against, the laboratory.

1 (3) REPORT TO CONGRESS.—Upon completion
2 of the feasibility study under this subsection, the
3 Federal official designated under subsection (a) shall
4 submit to the Congress a report on the results of
5 such study.

6 (f) DEFINITION.—In this section, the term “high-
7 containment laboratory” means laboratories that are suit-
8 able for “biosafety level 3” or “biosafety level 4” proce-
9 dures as defined in the latest edition of “Biosafety in
10 Microbiological and Biomedical Laboratories” published
11 by the Centers for Disease Control and Prevention and
12 the National Institutes of Health (or any successor to such
13 publication).